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Introduction to the Symposium

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SCIENCE FOR JUDGES VIII: INTRODUCTION

*Margaret A. Berger**

The Journal of Law and Policy is once again publishing extended versions of presentations made by speakers at a conference for federal and state judges on science and the law.¹ The conference, which took place at Brooklyn Law School on November 3 and 4, 2006, was the eighth in a series of Science for Judges programs funded by the Common Benefit Trust established in the Silicone Breast Implant Products Liability Litigation. It was held under the auspices of Brooklyn Law School's Center for Health, Science and Public Policy in collaboration with the Federal Judicial Center, the National Center for State Courts, and the Committee on Science, Technology and Law of the National Academies of Science.

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¹ Papers from previous Science for Judges programs can be found at 12 J.L. & POL'Y 1, 1-53 (2003) (papers discussing the practice of epidemiology and the science produced by administrative agencies); 12 J.L. & POL'Y 485, 485, 485-639 (2004) (papers discussing toxicology and epidemiology); 13 J.L. & POL'Y 1, 1-179 (2005) (papers discussing the integrity of scientific research and forensic evidence in criminal proceedings); 13 J.L. & POL'Y 499, 499-647 (2005) (papers discussing Agent Orange and human behavior research); and 14 J.L. & POL'Y 1, 1-209 (2006) (papers discussing risk assessment dealing with expert proof of causation in toxic tort cases and issues relevant to the availability of data); 14 J.L. & POL'Y 525, 525-616 (2006) (papers discussing evidence-based medicine); 15 J.L. & POL'Y 1, 1-164 (2007) (papers discussing the evidence of causation as well as current issues and standards of forensic laboratories). All papers are available in electronic form at <http://brooklaw.edu/centers/scienceforjudges/papers.php>.

This time, the program focused on pharmaceutical drugs and asbestos, two products whose use—past and present—raises troublesome issues for the American legal system. From a scientific perspective as well, the questions posed are complex and costly. In addition to their potent impact on public health and the litigation process, the issues surrounding pharmaceuticals and asbestos affect not only the courts but also congress and administrative agencies. The articles that follow view the resulting problems in a variety of different contexts that illustrate the myriad challenges and possible solutions that arise at the intersection of science and the law. An added bonus is that two of the papers provide us with a glimpse of how other legal systems react. Furthermore, these articles are extremely timely; they deal with current problems some of which may have received more coverage on the web than in law reviews.

The first article, by Dr. Drummond Rennie, looks at the pharmaceutical industry from the vantage point of a professor of medicine and a medical editor, who has worked at the two most prestigious general medical journals.² Dr. Rennie tells a sobering tale of how a changing academic culture led to enormous conflicts of interest once the Baye-Dole Act's passage in 1980, allowed universities to profit from scientific discoveries.³ The consequence, according to Dr. Rennie, has been research misconduct, the biased reporting of results, the burying of negative results, and the publishing of trials that ostensibly come from research universities but are actually produced by the companies sponsoring the studies. He also discusses changes at the FDA that have made it far more company-friendly. He offers numerous suggestions for what must be done in order for the pharmaceutical companies and the FDA to regain our trust. Dr. Rennie clearly believes that our present system—as formally constituted and implemented—does not adequately safeguard the public's health.

The next article by Professor Catherine Sharkey views the

² Drummond Rennie, *When Evidence Isn't: Trials, Drug Companies and the FDA*, 15 J.L. & POL'Y 991 (2007).

³ *Id.* at 997.

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problem of pharmaceuticals from a very different perspective.⁴ Even while the FDA was embroiled in a number of controversial cases,⁵ that led to its requesting a review by a committee of the National Academies' Institute of Medicine which has now published a highly critical report,⁶ the FDA was issuing a new rule for labeling prescription drugs. In the preamble to the new rule the FDA stated its view that the rule preempted competing state law regulatory and common law claims.⁷

Professor Sharkey's article examines the history of the preemption doctrine in the products liability realm in general, considers differences in the response of federal and state courts, and discusses the abandonment of the regulatory compliance defense in favor of the federal preemption doctrine. She then turns to the 2006 preemption claim by the FDA and analyzes the federal and state cases that have dealt with the issue. She finds, not surprisingly, that the federal courts have been more receptive to the FDA's position. Preemption is obviously a highly complex issue that implicates federalism concerns as well as the operation of deference to interpretations by administrative agencies. Although it is far too soon to know what the ultimate fate of the preemption defense will be, and its impact on toxic tort litigation involving pharmaceuticals, it seems safe to predict that Professor Sharkey's article will be the starting point for many discussions of this problem.

Professor Anita Bernstein's article proceeds on a completely different track.⁸ Although she notes that pharmaceutical

⁴ Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases In State Versus Federal Courts*, J.L. & POL'Y 1051 (2007).

⁵ RENNIE, *supra* note 2, at 1003-006.

⁶ Institute of Medicine, Committee on the Assessment of the US Drug Safety System, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (Anita Baciú, et al eds., National Academies Press, 2007).

⁷ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934, n. 7 (Jan 24, 2006) (effective date June 30, 2006).

⁸ Anita Bernstein, *Enhancing Drug Effectiveness and Efficacy Through*

companies have on the whole been affected very little by personal injury litigation, she is willing to assume that such litigation can cause harm to the drug industry and its customers. What Professor Bernstein seeks is a means by which prescription drug liability can play a positive role in improving the practices of the pharmaceutical industry. She makes the novel suggestion that courts consider "ineffectiveness" as an actionable injury instead of tying liability solely to a lack of safety. In Part I of her article she explores the meaning of effectiveness, including the difference between effectiveness and efficacy. Part II examines the harms caused to consumers by ineffective drugs that do not live up to promises on a label, and in Part III Professor Bernstein makes specific suggestions for modest first steps that courts could take when manufacturers make false promises. Her thesis promotes a fresh scrutiny of the pharmaceutical industry to determine whether the current system is in the public's best interest, and asks that we reconsider the role of the tort system.

The last article about pharmaceuticals by Robert Nakagawa, a member of the British Columbia Ministry of Health, discusses measures Canada has taken to reduce the price of prescription drugs.⁹ Each provincial government determines for which drugs they will provide payment. Safety and efficacy assessments enter into these determinations which British Columbia reaches by considering information generated by its extensive database which currently includes all prescriptions dispensed within province's pharmacies since 1995. The extensive database also operates to detect fraud and to identify emerging problems, such as harmful interactions caused by taking more than one drug. Many of the problems discussed in the preceding articles on pharmaceuticals could undoubtedly be avoided in the United States if more information were available on how the prescription drugs on the American market actually work.

The articles on asbestos are equally rich. It may surprise

Personal Injury Litigation, 15 J.L. & POL'Y 1051 (2007).

⁹ Robert S. Nakagawa, *Prescription Drug Systems and Price Control in Canada*, 15 J.L. & POL'Y 1103 (2007).

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some that more than fifty years after exposure to asbestos fibers was linked to cancers of the respiratory tract, and more than thirty years after asbestos litigation began, unresolved questions remained about asbestos and the causation of non-respiratory cancers. Dr. Jonathan Samet writes about the Institute of Medicine Committee he chaired which Congress charged with carrying out a study on the association of asbestos with colorectal, laryngeal, oropharyngeal, stomach, and esophageal cancers.¹⁰ Dr. Samet's discussion of the methodology used by the Committee, the reasons for uncertainties that remain, the classification system adopted by the Committee, and the Committee's findings will be of interest not only to those who deal with asbestos, but to all concerned with issues of causation from the legal or scientific perspective. As causation is the crucial problem in virtually all toxic tort litigation, this essay should attract many readers in a variety of disciplines.

The next article by Patrick Hanlon, which discusses the attempt to handle asbestos claims through federal legislation,¹¹ is related to the previous article by Dr. Samet. Congress had commissioned the Institute of Medicine study, because the information sought was needed to implement a congressional compensation scheme. Ultimately, as Mr. Hanlon relates, the proposed FAIR Act failed to pass. His explanation of the provisions in the bill, the numerous complex scientific questions that had to be addressed, and the policy issues that could not be resolved make fascinating reading. This is an article about science, law and politics. The descriptions of the various constituencies that had a stake in the bill and their reactions suggest that legislation may never be a viable option for reforming toxic tort litigation. In that case, of course, most decision-making will be left to the courts. Fortunately, the number of new asbestos claims has decreased dramatically for

¹⁰ Jonathan M. Samet, *Asbestos and Causation of Non-Respiratory Cancers: Evaluation by the Institute of Medicine*, 15 J.L. & POL'Y 1117 (2007).

¹¹ Patrick M. Hanlon, *Federal Asbestos Legislation: Wrestling with the Medical Issues*, 15 J.L. & POL'Y 1171 (2007).

reasons also explored by Mr. Hanlon.

David Michaels and Celeste Monforton examine instances in which the scientific literature on asbestos has been skewed by litigation generated science.¹² Looking almost exclusively at the literature on auto mechanics' exposure to asbestos in friction products, Michaels and Monforton could find only one new epidemiological study on disease risk for auto mechanics in the ten years following the Occupational Safety and Health Administration's ("OSHA") final asbestos standard.¹³ Nevertheless, 39 papers have been published that do not contain new scientific data. Of these, the authors identified 26 as litigation-generated papers which offer literature reviews and reanalyze in a manner that would be useful for litigation. Michaels and Monforton conclude that the result is that whichever side pays more has more papers published. What looks like a consensus in the scientific community is instead "an artifact of sponsorship."¹⁴ At least as troubling is Michaels' and Monforton's charge that government agencies like the Environmental Protection Agency ("EPA") and OSHA have been pressured to remove valuable information from publications that linked asbestos exposure to disease in auto mechanics.

The last paper on asbestos litigation in New South Wales, Australia, was submitted by Judge Lawrence O'Meally, the President of the Dust Diseases Tribunal of New South Wales.¹⁵ Australia apparently has an incidence of malignant mesothelioma—an asbestos signature disease—that is higher than that of any other country. Until the Tribunal was established, some claimants died before their claims were heard in court. Since 1989, these claims are now handled on an expedited basis

¹² David Michaels & Celeste Monforton, *How Litigations Shapes the Scientific Literature: Asbestos and Disease Among Auto Mechanics*, 15 J.L. & POL'Y 1127 (2007).

¹³ The reasons for why new research has not been done are explored *id.* at 1157-161.

¹⁴ *Id.* at 1166.

¹⁵ Hon. John Lawrence O'Meally, *Asbestos Litigation In New South Wales*, J.L. & POL'Y 1209 (2007).

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before the Tribunal, which is a parallel court system in which all cases are tried before a judge. All cases are subject to compulsory mediation. Judge O'Meally's paper examines some of the other provisions of the Act. He makes the astonishing statement that in some cases less than four *hours* elapse between the filing of a statement of claim and the conclusion of the case.¹⁶

The articles based on the eighth Science for Judges program illuminate how difficult it is to resolve issues relating to pharmaceuticals and asbestos. On top of the ordinary complexities posed when science and the law intersect are problems such as the conflicts of interest and unethical behavior attributable to the enormous sums at stake, political pressures, unsettled issues about federalism, and uncertainties about the appropriate role of administrative agencies and congress. New and better solutions are definitely needed, but these articles spell out the enormous obstacles that have to be overcome.

¹⁶ *Id.* at 1215.